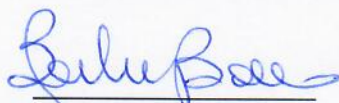


DECLARATION OF CONFORMITY ACCORDING TO THE DIRECTIVE 93/42/EEC

Manufacturer:	ZHERMACK SPA VIA BOVAZECCHINO, 100 45021 BADIA POLESINE (RO) ITALY			
Authorized EU-representative:	Not applicable			
PRODUCT CODE / CATALOGUE NUMBER	NAME	PACKAGING	CLASSIFICATION	RULE
C200750	COLORBITE D	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200760	COLORBITE ROCK	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200726	OCCLUFAST ROCK	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200727	OCCLUFAST ROCK	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C203220	OCCLUFAST ROCK	1x50 ml cartridge (Base + Catalyst)	Class I	Rule 5
C200800	OCCLUFAST CAD	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200790	OCCLUFAST+	1x50 ml cartridge (Base + Catalyst) + 6 mixing tips	Class I	Rule 5
C200791	OCCLUFAST+	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200792	OCCLUFAST+	8x50 ml cartridges (Base + Catalyst)	Class I	Rule 5
C200780	OCCLUFAST+ COLOR	1x50 ml cartridge (Base + Catalyst) + 6 mixing tips	Class I	Rule 5
C200781	OCCLUFAST+ COLOR	2x50 ml cartridges (Base + Catalyst) + 12 mixing tips	Class I	Rule 5
C200782	OCCLUFAST+ COLOR	8x50 ml cartridges (Base + Catalyst)	Class I	Rule 5
Classification Rules acc:	ANNEX IX OF THE MDD 93/42/EEC amended by 2007/47/EC			
Intended use:	Vinylpolysiloxane bite registration material			
WE HEREWITHTH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AMENDED BY 2007/47/EC FOR MEDICAL DEVICES, IN ACCORDANCE WITH THE ANNEXES I, VII, X, XII. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER. THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.				
Standards applied:	EN ISO 13485: 2016 EN ISO 14971: 2012 ISO 10993-1: 2009 EN 1041: 2008+A1: 2013 ISO 15223-1: 2016			
Technical standards ref.:	/			
EC certificate:	Not applicable			

Zhermack S.p.A.
Via Bovazecchino, 100
45021 – Badia Polesine (RO)

Badia Polesine, 23.04.2021



Barbara Baruzzo
QA/RA Manager



Zhermack S.p.A.